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PATENT REQUEST : STANDARD PATENT

I/We, being the person(s) identified below as the Applicant(s), request the grant of a Standard Patent to the person(s) identified below as the Nominated Person(s), for an invention described in the accompanying complete specification.

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Nominated Person(s):** C.I.R.D. GALDERMA

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Invention Title: NEW TOPICAL COMPOSITIONS IN THE FORM OF AN O/W
FLUID EMULSION WITH A HIGH CONTENT OF PRO-
PENETRATING GLYCOL

**Name(s) of Actual
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BASIC CONVENTION APPLICATION DETAILS

Application No:
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NOTICE OF ENTITLEMENT

lWe C.I.R.D. GALDERMA

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being the applicant(s) in respect of an application for a patent for an invention entitled **NEW TOPICAL COMPOSITIONS IN THE FORM OF AN O/W FLUID EMULSION WITH A HIGH CONTENT OF PRO-PENETRATING GLYCOL**, state the following:

1. The nominated person(s) has/have, for the following reasons, gained entitlement from the actual inventor(s):

**THE NOMINATED PERSON WOULD BE ENTITLED TO HAVE
ASSIGNED TO IT A PATENT GRANTED TO ANY OF THE
ACTUAL INVENTORS IN RESPECT OF THE SAID
INVENTION.**

2. The nominated person(s) has/have, for the following reasons, gained entitlement from the basic applicant(s) listed on the patent request:

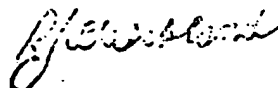
**THE APPLICANT AND NOMINATED PERSON IS THE BASIC
APPLICANT.**

3. The basic application(s) listed on the request form is/are the first application(s) made in a Convention country in respect of the invention.

DATE: 16 September 1997

C.I.R.D. GALDERMA

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**R. J. STRICKLAND
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on behalf of the applicant(s)**



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- (57) Claim

1. Composition in the form of an oil-in-water (O/W) type fluid emulsion for topical application, comprising between 30 and 50% by weight relative to the total weight of the composition of at least one glycol, an appropriate emulsifying system and at least one active agent.

3. Composition according to either of Claims 1 and 2, characterized in that the appropriate emulsifying system comprises at least one polymeric emulsifier.

4. Composition according to Claim 3, characterized in that the polymeric emulsifier is an anionic amphiphilic polymer, more particularly an anionic amphiphilic polymer comprising at least one hydrophilic unit of the olefin unsaturated carboxylic acid type, and at least one hydrophobic unit of the C₁₀-C₃₀ alkyl ester type.

6. Composition according to either of Claims 4 and 5, characterized in that the anionic amphiphilic polymer is chosen from (i) those which consist of 95 to 60% by weight of acrylic units, of 4 to 40% by weight of acrylate units and of 0.1 to 6% by weight of cross-linking monomer, or (ii) those which consist of 98 to 96% by weight of acrylic units, of 1 to 4% by weight of acrylate units and of 0.1 to 0.6% by weight of cross-linking monomer.

10. Composition according to one of Claims 1 to 9, characterized in that the active agent is chosen from the agents modulating skin differentiation and/or proliferation and/or pigmentation, antibacterial agents, antiparasitic agents, antifungal agents, steroidal anti-inflammatory agents or non-steroidal anti-inflammatory agents, anaesthetic agents, antipruritic agents, antiviral agents, keratolytic agents, anti-free radical agents, antiseborrhoeic agents, antidandruff agents, anti-acne agents, antimetabolites, agents for combating hair loss, and antiseptics.

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COMPLETE SPECIFICATION
STANDARD PATENT

Applicant(s):

C.I.R.D. GALDERMA

Invention Title:

NEW TOPICAL COMPOSITIONS IN THE FORM OF AN O/W FLUID EMULSION
WITH A HIGH CONTENT OF PRO-PENETRATING GLYCOL

The following statement is a full description of this
invention, including the best method of performing it known to
me/us:

The present invention relates to a new composition in the form of an oil-in-water (O/W) type fluid emulsion for topical application, comprising a high content of at least one pro-penetrating glycol, an appropriate emulsifying system and an active agent.

There are currently numerous topical compositions comprising an active agent and a high content of glycol, the latter promoting the penetration of the active agent into the skin. Given the high content of pro-penetrating glycol, these compositions are formulated in the form of emulsions with a high content of fatty phase which are also commonly called "lipocreams", in the form of anhydrous compositions which are called "ointments", in the form of fluid compositions with a high content of volatile solvents, such as ethanol or isopropanol, which are intended for application to the scalp, which are also called "hair lotions", or alternatively in the form of viscous O/W emulsions which are also called "O/W creams".

O/W creams comprising a corticoid and a high percentage of propylene glycol (47.5%), which are marketed under the trade mark TEMOVATE® by the company GLAXO, are known for example. Now, the stabilization of a formulation comprising such a percentage of glycol necessitates the use, in the emulsion, of emulsifying and stabilizing agents of the glyceryl stearate or PEG 100 stearate type or alternatively of stabilizing agents or consistency factors of the white wax or

ketostearyl alcohol type which lead to the formation of a viscous cream, that is to say whose viscosity is greater than 10 Pa.s (10,000 centipoises, measured with a Brookfield apparatus model LVDV II + rotor No. 4, at a speed of 30 revolutions/min for 30 seconds and at a temperature of $25^{\circ}\text{C} \pm 3^{\circ}\text{C}$).

To facilitate the application of topical compositions comprising a high percentage of glycol, it was advantageous to have a new stable formulation of the O/W emulsion type, whose viscosity would be intermediate between the hair lotions which are too fluid and whose use is too limited, and the O/W creams which are too viscous and which have a fatty and sticky characteristic, while preserving the pro-penetrating properties of the glycol.

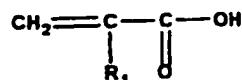
The present invention therefore relates to a new composition in the form of an oil-in-water (O/W) type fluid emulsion for topical application, comprising between 30 and 50% by weight relative to the total weight of the composition of at least one glycol, an appropriate emulsifying system and at least one active agent.

Fluid emulsion is understood to mean advantageously an emulsion whose viscosity is between 3 and 10 Pa.s (3000 and 10,000 centipoises), a viscosity measured with a Brookfield apparatus model LVDV II + rotor No. 4, at a speed of 30 revolutions/min for 30 seconds and at a temperature of $25^{\circ}\text{C} \pm 3^{\circ}\text{C}$.

Advantageously, a stable emulsion is obtained according to the invention by selecting, as appropriate emulsifying system, at least one polymeric emulsifier. The polymeric emulsifiers are in particular described
 5 by CLYMANS & BRAND in "Cosmetics and Toiletries (manufacture worldwide, 1995, 119-125).

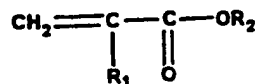
They are in particular anionic amphiphilic polymers, more particularly those comprising at least one hydrophilic unit of the olefin unsaturated
 10 carboxylic acid type, and at least one hydrophobic unit of the C₁₀-C₃₀ alkyl ester type.

According to the invention, it is intended to designate as acrylic units those of formula



in which R₁ designates H or CH₃ or C₂H₅, that is to say
 15 acrylic acid, methacrylic acid or ethacrylic acid units.

It is also intended to designate as alkyl acrylate units those of structure:



in which R₁ designates H or CH₃ or C₂H₅, that is to say
 20 acrylate, methacrylate or ethacrylate units, R₂ designating a C₁₀-C₃₀, preferably C₁₂-C₂₂, alkyl radical.

Acrylates in accordance with the invention

comprise, for example, lauryl acrylate, stearyl
acrylate, decyl acrylate, isodecyl acrylate, dodecyl
acrylate and the corresponding methacrylates, lauryl
methacrylate, stearyl methacrylate, decyl methacrylate,
5 isodecyl methacrylate and dodecyl methacrylate.

Preferably, the above anionic amphiphilic
polymers are cross-linked with a cross-linking
polymerizable monomer containing a $\text{CH}_2=\text{C}$ group with at
least one other polymerizable group whose unsaturated
10 bonds are not conjugated relative to each other.

Cross-linking polymerizable monomers of the
type are for example, and preferably, polyallyl ethers
such as in particular polyallylsucrose and
polyallylpentaerythritol.

15 The cross-linked polymers of this type are
well known; they are in particular described in Patents
US-3,915,921 and US 4,509,949.

According to the invention, there may more
particularly be used as anionic amphiphilic polymers,
20 (i) those which consist of 95 to 60% by weight of
acrylic units, of 4 to 40% by weight of acrylate units
and of 0.1 to 6% by weight of cross-linking monomer, or
(ii) those which consist of 98 to 96% by weight of
acrylic units, of 1 to 4% by weight of acrylate units
25 and of 0.1 to 0.6% by weight of cross-linking monomer.

Among the said cross-linked polymers above,
the products sold by the company GOODRICH under the
trade names PEMULEN TR1, PEMULEN TR2, CARBOPOL 1342 or

CARBOPOL 1382, are most particularly preferred according to the present invention.

The composition according to the invention advantageously comprises up to 1% by weight of appropriate emulsifying system, preferably between 0.2 and 0.4% by weight relative to the total weight of the composition.

The pro-penetrating glycol is advantageously chosen from propylene glycol, dipropylene glycol, propylene glycol dipelargonate, lauroglycol or ethoxydiglycol.

Preferably, the composition according to the invention comprises between 40 and 50% by weight of pro-penetrating glycol.

Among the active agents, there may be mentioned, by way of example, the agents modulating skin differentiation and/or proliferation and/or pigmentation such as retinoic acid and its isomers, retinol and its esters, retinal, retinoids, in particular those described in Patent Applications FR 2,570,377, EP 199 636, EP 325 540, EP 402 072, vitamin D and its derivatives, oestrogens such as oestradiol, kojic acid or hydroquinone; antibacterial agents such as clindamycin phosphate, erythromycin or the tetracyclin class of antibiotics; antiparasitic agents, in particular metronidazol, crotamiton or pyrethrinoids; antifungal agents, in particular compounds belonging to the class of imidazoles such as

econazole, ketoconazole or miconazole or their salts, polyene compounds such as amphotericin B, compounds of the family of allylamines, such as terbinafine or alternatively octopirox; steroidal anti-inflammatory agents such as hydrocortisone, anthralins (dioxyanthranol), anthranoids, betamethasone valerate or clobetasol propionate, or non-steroidal anti-inflammatory agents such as ibuprofen and its salts, diclofenac and its salts, acetylsalicylic acid, acetaminophen or glycyrrhetic acid; anaesthetic agents such as lidocaine hydrochloride and its derivatives; antipruritic agents such as thenaldine, trimeprazine or cyproheptadine; antiviral agents such as acyclovir; keratolytic agents such as alpha- and beta-hydroxycarboxylic or betaketocarboxylic acids, their salts, amides or esters and more particularly the hydroxy acids such as glycolic acid, lactic acid, malic acid, salicylic acid, citric acid and, in general, the fruit acids, and 5-n-octanoylsalicylic acid; anti-free radical agents such as alpha-tocopherol or its esters, superoxide dismutases, certain metal chelators or ascorbic acid and its esters; antiseborrhoeic agents such as progesterone; antidandruff agents such as octopirox or zinc pyrithione; anti-acne agents such as retinoic acid, benzoyl peroxide or adapalene; antimetabolites; agents for combating hair loss such as minoxidil; antiseptics.

Advantageously, the composition according to

the invention comprises between 0.0001 and 20% by weight relative to the total weight of the composition of an active agent, preferably between 0.025 and 15% by weight.

5 Of course the quantity of active agent in the composition according to the invention will depend on the active agent considered. Thus, for a steroidal anti-inflammatory agent, the composition according to the invention will advantageously comprise less than 1%
10 by weight of active agent, preferably between 0.025 and 0.05% by weight. For the hydroquinones, the composition according to the invention will preferably comprise between 2 and 5% of active agent. For the antibacterial or antifungal agents such as econazole, the composition
15 according to the invention will preferably comprise between 8 and 10% by weight of active agent.

The fatty phase of the emulsion according to the invention may comprise fatty substances normally used in the field of application envisaged.

20 Among these, there may be mentioned the silicone fatty substances such as the silicone oils, as well as the non-silicone fatty substances such as the vegetable, mineral, animal or synthetic oils.

 Among the silicone fatty substances, there
25 may be mentioned:

- (i) the poly(C₁-C₂₀ alkyl)siloxanes and in particular those with trimethylsilyl terminal groups, preferably those whose viscosity is less than 0.06 m²/s

among which there may be mentioned the linear polydimethylsiloxanes and the alkylmethylpolysiloxanes such as cetyldimethicone (CTFA name),

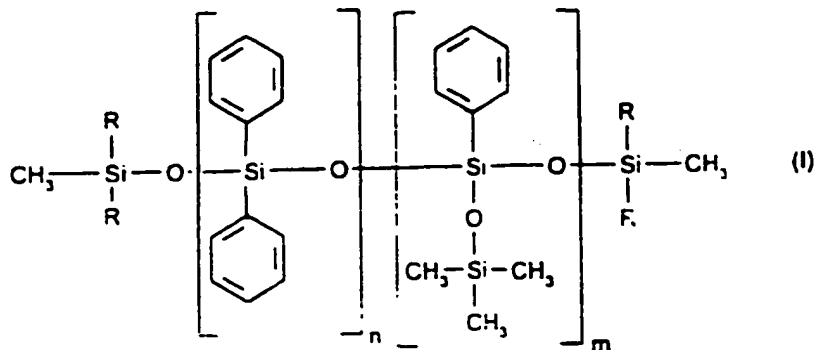
- (ii) the volatile silicone oils, such as:

5 - the cyclic volatile silicones having from 3 to 8 silicon atoms and preferably from 4 to 5. They are for example cyclotetradimethylsiloxane, cyclopentadimethylsiloxane or cyclohexadimethylsiloxane,

10 - the cyclocopolymers of the dimethylsiloxane/methylalkylsiloxane type, such as SILICONE FZ 3109 sold by the company UNION CARBIDE, which is a dimethylsiloxane/methyloctylsiloxane cyclocopolymer,

15 - the linear volatile silicones having from 2 to 9 silicon atoms. They are for example hexamethyldisiloxane, hexyl heptamethyltrisiloxane or octyl heptamethyltrisiloxane,

20 - (iii) the phenylated silicone oils, in particular those of formula:



in which

· R is a C_1 - C_{10} alkyl radical, an aryl radical or an aralkyl radical,

· n is an integer between 0 and 100,

5 · m is an integer between 0 and 100, provided that the sum is between 1 and 100.

Among the non-silicone fatty substances, there may be mentioned the customary oils such as paraffin oil, petroleum jelly, almond oil,
 10 perhydrosqualene, apricot oil, wheat germ, sweet almond, calophyllum, palm, castor, avocado, jojoba, olive or cereal germ oil; esters of fatty acids or of fatty alcohols, such as octyl dodecyl myristate or C_{12} - C_{15} alkyl benzoates, alcohols; acetylglycerides;
 15 octanoates, decanoates or ricinoleates of alcohols or of polyalcohols; triglycerides of fatty acids; glycerides; hydrogenated polyisobutene, hydrogenated oils which are concrete at 25°C; lanolins; fatty esters which are concrete at 25°C.

20 These fatty substances may in particular be chosen in a variety of ways by persons skilled in the art so as to prepare a composition having the desired properties, for example as regards consistency or texture.

25 Thus, the fatty phase of the emulsion according to the invention may be present in an amount of between 5 and 50% by weight relative to the total weight of the composition, and preferably between 15

and 25% by weight.

The aqueous phase of the emulsion according to the invention may comprise water, a floral water such as cornflower water, or a natural mineral or thermal water, for example chosen from Vittel water, water from the Vichy basin, Uriage water, Roche Posay water, Bourboule water, Enghien-les-Bains water, Saint Gervais-les-Bains water, Nérès-les-Bains water, Allevard-les-Bains water, Digne water, Maizières water, Neyrac-les-Bains water, Lons-le-Saunier water, Bonnes water, Rochefort water, Saint Christau water, Fumades water, Tercis-les-bains water, Avène water or Aix les Bains water.

The said aqueous phase may be present in an amount of between 10 and 70% by weight relative to the total weight of the composition, preferably between 20 and 40% by weight.

The pH of the composition according to the invention is advantageously between 5 and 7, preferably between 5.5 and 6.5. It will be adjusted to the desired value by adding customary inorganic or organic bases or acids.

Moreover, the composition according to the invention may comprise between 0 and 3% by weight, preferably between 0 and 2% by weight, relative to the total weight of the composition, of at least one co-emulsifier which may be chosen from esters of saturated or unsaturated fatty acids, which are natural

or synthetic, in particular oleic acid or (iso)stearic acid, such as the esters of polyglycerin and isostearic acid which are marketed under the trade mark LAMEFORM TGI by the company SIDOBRE-SINNOVA HENKEL, 5 sorbitan isostearate marketed under the trade mark ARLACEL 987 by the company ICI, sorbitan sesquioleate marketed under the trade mark ARLACEL 83 by the company ICI, the esters of glycol and isostearic acid such as PEG-6 isostearate marketed under the trade mark OLEPAL 10 ISOSTEARIQUE by the company GATTEFOSSE, the esters of sorbitol and oleic acid such as the polysorbates marketed under the trade mark TWEEN by the company JCI, the fatty alcohol ethers, in particular oleyl alcohol, in particular the esters of glycol and oleyl alcohol, 15 such as the oleths marketed under the trade mark BRIJ by the company ICI, oxyethylenated sorbitan monostearate, the fatty alcohols such as stearyl alcohol or cetyl alcohol.

In addition, the composition according to the 20 invention may comprise at least one gelling and/or thickening agent in preferred concentrations of between 0 and 5% by weight relative to the total weight of the composition.

The gelling and/or thickening agent may be 25 chosen from:

- the polysaccharide biopolymers such as xanthan gum, carob gum, guar gum, alginates, modified cellul ses such as hydroxyethylcellulose,

methylcellulose, hydroxypropylcellulose, hydroxypropyl-methylcellulose and carboxymethylcellulose,

- the synthetic polymers such as the polyacrylic acids such as glyceryl poly(meth)acrylate polymers such
5 as HISPAGEL or LUBRAGEL from the companies HISPANO QUIMICA or GARDIAN, polyvinylpyrrolidone, polyvinyl alcohol, the cross-linked polymers of acrylamide and ammonium acrylate such as PAS 5161 or BOZEPOL C from HOECHST, the cross-linked polymers of acrylamide and
10 partially or completely neutralized 2-acrylamido-2-methylpropanesulphonic acid such as SEPIGEL 305 from SEPPIC, the cross-linked polymers of acrylamide and methacryloyloxyethyltrimethylammonium chloride such as SALCARE SC 92 from ALLIED COLLOIDS, the cross-linked
15 polymers of acrylic acid and alkyl ethers of sucrose or of pentaerythritol (carbomers) such as CARBOPOL 910 to 934 from GOODRICH.

The emulsion may comprise, in addition, any additive customarily used in the cosmetic or
20 pharmaceutical field, such as antioxidants, colorants, perfumes, essential oils, preservatives, cosmetic active agents, moisturizers, vitamins, essential fatty acids, sphingolipids, self-tanning compounds such as DHA, sunscreens agents, fat-soluble polymers, in
25 particular those which contain hydrocarbons, such as polybutene, polyalkylenes, polyacrylates and silicone polymers which are compatible with fatty substances. Of course, persons skilled in the art will be careful to

choose this or these possible additional compound(s),
and/or their quantity, such that the advantageous
properties of the composition according to the
invention are not, or not substantially, altered by the
5 addition envisaged.

These additives may be present in the
composition in an amount of 0 to 10% by weight relative
to the total weight of the composition.

The examples of formulations below make it
10 possible to illustrate the compositions according to
the invention without, however, limiting its scope. The
quantities of the constituents are expressed in % by
weight relative to the total weight of the composition.

Example 1 Example of formulation according to the

15 invention

	COMPOSITION	% by weight
	Purified water	qs 100
	Hydroxypropylmethylcellulose	0.10
	Propylene glycol	47.50
20	Active agent	0.05
	Liquid paraffin 110-230	20.00
	Acrylate/C ₁₀ -C ₃₀ alkyl acrylate crosspolymer (marketed under the trade mark PEMULEN TR-2 by the 25 company GOODRICH)	0.30
	PEG-6 isostearate	2.00
	NaOH, 10%	qs pH 6

In this formulati n, the active agent

remained stable for at least 3 months at 40°C.

Example 2 Activity of the formula with clobetasol
propionate

The above formula according to the invention
5 was used with clobetasol propionate as active agent.

Vasoconstriction tests according to the
modified Stoughton protocol were performed in
comparison with the corresponding O/W cream marketed
under the trade mark TEMOVATE by the company GLAXO.

10 The results show an identical activity for
the two formulae, which confirms that despite the
modification of the viscosity of the formulation
according to the invention and the use of a different
emulsifying system, the pro-penetrating glycol retained
15 its pro-penetrating properties.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. Composition in the form of an oil-in-water (O/W) type fluid emulsion for topical application, comprising between 30 and 50% by weight
5 relative to the total weight of the composition of at least one glycol, an appropriate emulsifying system and at least one active agent.

2. Composition according to Claim 1, characterized in that it has a viscosity of between 3
10 and 10 Pa.s (3000 and 10,000 centipoises), a viscosity measured with a Brookfield apparatus model LV DV II + rotor No. 4, at a speed of 30 revolutions/min for 30 seconds and at a temperature of $25^{\circ}\text{C} \pm 3^{\circ}\text{C}$.

3. Composition according to either of
15 Claims 1 and 2, characterized in that the appropriate emulsifying system comprises at least one polymeric emulsifier.

4. Composition according to Claim 3,
characterized in that the polymeric emulsifier is an
20 anionic amphiphilic polymer, more particularly an anionic amphiphilic polymer comprising at least one hydrophilic unit of the olefin unsaturated carboxylic acid type, and at least one hydrophobic unit of the C_{10} - C_{30} alkyl ester type.

5. Composition according to Claim 4,
25 characterized in that the anionic amphiphilic polymers are cross-linked with a cross-linking polymerizable monomer containing a $\text{CH}_2=\text{C}<$ group with at least one

other polymerizable group whose unsaturated bonds are not conjugated relative to each other in particular with polyallyl ethers such as polyallylsucrose and polyallylpentaerythritol.

5 6. Composition according to either of Claims 4 and 5, characterized in that the anionic amphiphilic polymer is chosen from (i) those which consist of 95 to 60% by weight of acrylic units, of 4 to 40% by weight of acrylate units and of 0.1 to 6% by weight of cross-linking monomer, or (ii) those which
10 consist of 98 to 96% by weight of acrylic units, of 1 to 4% by weight of acrylate units and of 0.1 to 0.6% by weight of cross-linking monomer.

15 7. Composition according to one of Claims 1 to 6, characterized in that it comprises up to 1% by weight of appropriate emulsifying system, preferably between 0.2 and 0.4% by weight.

20 8. Composition according to one of Claims 1 to 7, characterized in that the pro-penetrating glycol is chosen from propylene glycol, dipropylene glycol, propylene glycol dipelargonate, lauroglycol or ethoxydiglycol.

25 9. Composition according to one of Claims 1 to 8, characterized in that it comprises between 40 and 50% by weight of pro-penetrating glycol.

10. Composition according to one of Claims 1 to 9, characterized in that the active agent is chosen from the agents modulating skin differentiation and/or

proliferation and/or pigmentation, antibacterial agents, antiparasitic agents, antifungal agents, steroidal anti-inflammatory agents or non-steroidal anti-inflammatory agents, anaesthetic agents, antipruritic agents, antiviral agents, keratolytic agents, anti-free radical agents, antiseborrhoeic agents, antidandruff agents, anti-acne agents, antimetabolites, agents for combating hair loss, and antiseptics.

10 11. Composition according to one of Claims 1 to 10, characterized in that it comprises between 0.0001 and 20% by weight relative to the total weight of the composition of at least one active agent, preferably between 0.025 and 15% by weight.

15 12. Composition according to one of Claims 1 to 11, characterized in that the fatty phase is present in an amount of between 5 and 50% by weight relative to the total weight of the composition, preferably between 15 and 25% by weight.

20 13. Composition according to one of Claims 1 to 12, characterized in that the aqueous phase is present in an amount of between 10 and 75% by weight relative to the total weight of the composition, preferably between 20 and 40% by weight.

25 14. Composition according to one of Claims 1 to 13, characterized in that it comprises between 0 and 3% by weight relative to the total weight of the composition, of at least one co-emulsifier, preferably

0 and 2% by weight.

15. Composition according to one of Claims 1
to 14, characterized in that it comprises at least one
gelling and/or thickening agent in concentrations of
5 between 0 and 5% by weight relative to the total weight
of the composition.

DATED THIS 16TH DAY OF SEPTEMBER 1997

C.I.R.D. GALDERMA

By its Patent Attorneys:

GRIFFITH HACK

Fellows Institute of Patent
Attorneys of Australia

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DESCRIPTIVE ABSTRACT

NEW TOPICAL COMPOSITIONS IN THE FORM OF AN O/W FLUID EMULSION WITH A HIGH CONTENT OF PRO-PENETRATING GLYCOL

The present invention relates to a new composition in the form of an oil-in-water (O/W) type fluid emulsion for topical application, comprising between 30 and 50% by weight relative to the total weight of the composition of at least one glycol, an appropriate emulsifying system and at least one active agent. The fluid composition according to the invention preferably has a viscosity of between 3 and 10 Pa.s (3000 and 10,000 centipoises), a viscosity measured with a Brookfield apparatus model LVDV II + rotor No. 4, at a speed of 30 revolutions/min for 30 seconds and at a temperature of $25^{\circ}\text{C} \pm 3^{\circ}\text{C}$.